

TOPEX- benzocaine spray, metered
Dentsply LLC. Professional Division Trading as "Sultan Healthcare "

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).

Topex
Topical Anesthetic
Metered Spray

INDICATIONS AND USAGE

Topical anesthetic for use on oral mucosa

DOSAGE AND ADMINISTRATION

Attach disposable straw to the spray valve. Spray directly on mucosa to achieve topical anesthesia.

DOSAGE FORMS AND STRENGTHS

Each gram of Topex 20% benzocaine topical anesthetic spray contains between 180-220 mg benzocaine. Each metered spray delivers approximately 6.8 mg of benzocaine.

CONTRAINDICATIONS

Should not be used in individuals with a known sensitivity to benzocaine or PABA.

WARNINGS AND PRECAUTIONS

METHEMOGLOBINEMIA WARNING:

Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient in your care develops:

- pale, gray, or blue colored skin (cyanosis),
 - headache,
 - rapid heart rate,
 - shortness of breath,
 - dizziness or lightheadedness,
 - fatigue or lack of energy
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- Not for use in children under 2 years of age.
 - Keep out of reach of children.

OVERDOSAGE

In case of overdose, get medical help or contact a Poison Control Center right away.

STORAGE AND HANDLING

Store between 59°-86°F (15°-30°C).

PRINCIPAL DISPLAY PANEL - Carton

<p>INDICATIONS AND USAGE Topical anesthetic for use on oral mucosa.</p> <p>DOSAGE AND ADMINISTRATION Attach disposable straw to the spray valve. Spray directly on mucosa to achieve topical anesthesia.</p> <p>DOSAGE FORMS AND STRENGTH Each gram of Topex 20% benzocaine topical anesthetic spray contains between 180-220 mg benzocaine. Each metered spray delivers approximately 6.8 mg of benzocaine.</p> <p>CONTRAINDICATIONS Should not be used in individuals with a known sensitivity to benzocaine or PABA.</p> <p>WARNINGS AND PRECAUTIONS METHEMOGLOBINEMIA WARNING: Use of this product may cause methemoglobinemia, a rare but serious condition that must be treated promptly because it reduces the amount of oxygen carried in blood. Stop use and seek immediate medical attention if the patient in your care develops: pale, gray, or blue colored skin (cyanosis), headache, rapid heart rate, shortness of breath, dizziness or lightheadedness, fatigue or lack of energy.</p> <ul style="list-style-type: none">• Not for use in children under 2 years of age.• Keep out of reach of children. <p>OVERDOSAGE In case of overdose, get medical help or contact a Poison Control Center right away.</p> <p>INGREDIENTS Heptafluoropropane (Propellant), Denatured Ethyl Alcohol (Benzaldehyde), Benzocaine, Polyethylene Glycol 400, Sodium Saccharin, Artificial Cherry Flavor</p> <p>STORAGE Store between 59°-86°F (15°-30°C)</p>	<p>Manufactured For: Sultan Healthcare 1301 Smile Way York, PA 17404</p> <p>Toll Free: 800-637-8582 Phone: 201-871-1232 Fax: 201-871-0321 www.sultanhealthcare.com</p> <p>0031000BX, R3-072017</p>	<p></p> <p>Topex[®] Topical Anesthetic Metered Spray</p> <p>Contains: 20% Benzocaine</p> <p> WILD CHERRY</p> <p>Rx Only</p> <p>Net Weight: 2 oz (57g)</p> <p>REF AD31000 NDC 0699-3100-02</p>	<p>Includes: 25 dispensing tips</p> <p></p> <p>Danger: Extremely flammable aerosol. Contains gas under pressure; may explode if heated. May cause an allergic skin reaction. Causes serious eye irritation.</p>
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TOPEX

benzocaine spray, metered

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0699-3100
Route of Administration	PERIODONTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOCAINE (UNII: U3RSY48JW5) (BENZOCAINE - UNII:U3RSY48JW5)	BENZOCAINE	220 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
BENZALDEHYDE (UNII: TA269SD04T)	
APAFLURANE (UNII: R40P36GDK6)	

Product Characteristics				
Color		Score		
Shape		Size		
Flavor	CHERRY	Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0699-3100-02	1 in 1 CARTON	01/01/1900	
1		57 g in 1 CANISTER; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		01/01/1900		

Labeler - Dentsply LLC. Professional Division Trading as "Sultan Healthcare" (167087753)

Establishment			
Name	Address	ID/FEI	Business Operations
Sciarra Laboratories, Inc.		824900369	manufacture(0699-3100)